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510(K) SUMMARY

NOV - 7 2008

Date Prepared:	November 3, 2008
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 8200 Coral Sea Street NE Mounds View, MN 55112
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Proprietary Name:	Reveal XT Insertable Cardiac Monitor, Model 9529 Reveal XT Patient Assistant 9539 Reveal DX Insertable Cardiac Monitor, Model 9528 Reveal DX Patient Assistant 9538
Common Name:	Insertable Cardiac Monitor
Device Classification	Class II, 21 CFR 870.1025, Arrhythmia detector and alarm
Product Code:	DSI

Summary of Substantial Equivalence

The intended use, design, materials and performance of the Reveal XT Model 9529 and Reveal DX Model 9528 Insertable Cardiac Monitors are substantially equivalent to the following predicate devices:

- Medtronic Reveal XT Model 9529 Insertable Cardiac Monitor (ICM) cleared via 510k reference K071641 and the Reveal DX Model 9528 Insertable Cardiac Monitor cleared via 510k reference K071655 on August 9, 2007.
- Instromedix King of Hearts Express AF Recorder - K020825, Cleared 05 April 2002

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Device Description

The Reveal XT Model 9529 and Reveal DX Model 9528 Insertable Cardiac Monitors (ICM) are designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial tachyarrhythmia/atrial fibrillation (AT/AF), bradyarrhythmia, asystole, or (fast) ventricular tachyarrhythmia. The Reveal XT ICM provides storage of ECG and Marker Channel during patient-activated and automatically-detected (auto-activated) events. Auto activation may help to detect abnormal heart rhythms in patients who may not activate/trigger the ICM.

The Reveal XT ICM Model 9529 and Reveal DX Model 9528 are small, leadless devices that are typically implanted under the skin, in the chest. Two electrodes on the body of the device continuously monitor the patient's subcutaneous ECG.

The Reveal XT Patient Assistant Model 9539 and the Reveal DX Patient Assistant Model 9538 are hand-held, battery-operated telemetry devices that enable the patient to start recording cardiac information in the Reveal XT and DX ICMs, respectively after experiencing symptoms of a possible cardiac event. The Reveal XT Patient Assistant query function enables the patient to check the status of physician-programmed parameters. A query function enables the patient to check his or her device and receive notification when an arrhythmia has occurred or when the device status has changed.

Indications for Use

The Reveal XT and DX Insertable Cardiac Monitors are implantable patient-activated and automatically-activated monitoring systems that record subcutaneous ECG and are indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia.

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event.
- To initiate recording of cardiac event data in the implanted device memory.

Technological Characteristics

Intended use, design, materials, performance and technological characteristics are substantially equivalent to the predicate devices referenced.

Summary of Testing

There are no changes to the hardware, materials, processes, packaging, shelf life and sterilization of the Reveal XT and Reveal DX Systems included in this submission. Therefore, electromagnetic compatibility (EMC), electrical safety, mechanical performance, component, usability, biocompatibility, sterilization and packaging testing was not repeated since 510k clearance via K071641 and K071655.

Software and system verification testing, system validation testing, functional testing and performance validation testing (bench) was performed to demonstrate the Reveal XT Model 9529 Insertable Cardiac Monitor meets established performance criteria and to support equivalency to the reference predicate devices.

The results of the testing indicate that the Reveal XT Insertable Cardiac Monitor Model 9529 performs as intended and is safe for its intended use.

Conclusion

Medtronic considers the Reveal XT and Reveal DX Insertable Cardiac Monitor systems to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

Medtronic, Inc.
Ms. Debbie Kidder
Senior Regulatory Affairs Specialist
Cardiac Rhythm Disease Management
8200 Coral Sea Street, N.E.
Mounds View, MN 55112

Re: K082475
Trade/Device Name: Reveal XT Insertable Cardiac Monitor and Reveal XT Patient Assistant; Reveal DX Insertable Cardiac Monitor and Reveal DX Patient Assistant
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: October 7, 2008
Received: October 8, 2008

Dear Ms. Kidder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be

advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ashley B. Boam

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): _______________

Device Name: Reveal XT Insertable Cardiac Monitor and Reveal XT Patient Assistant
Reveal DX Insertable Cardiac Monitor and Reveal DX Patient Assistant

Indications for Use: The Reveal XT/DX Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias.
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia.

The Reveal XT/DX Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event. *
- To initiate recording of cardiac event data in the implanted device memory.

**only applicable to the Reveal XT Patient Assistant Model 9539*

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley Brown for BDZ
(Division Sign-Off)
Division of Cardiovascular Devices

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